UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 22, 2023**

CYCLERION THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Massachusetts	**001-38787**	**83-1895370**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

245 First Street, 18th Floor
Cambridge, Massachusetts 02142
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(857) 327-8778**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, no par value	CYCN	The Nasdaq Capital Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 22, 2023, Cyclerion Therapeutics, Inc. (the "Company") issued a press release announcing its financial and operating results for the year end 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K, which, in its entirety, is incorporated herein by reference.

The information set forth in this Item 2.02 is being furnished pursuant to Item 2.02 of Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or under the Exchange Act, whether made before or after the date hereof, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description
99.1	Press Release of Cyclerion Therapeutics, Inc. dated March 22, 2023
104	Cover Page Interactive Data File

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cyclerion Therapeutics, Inc.

Dated: March 22, 2023

By: /s/ Anjeza Gjino

Name: Anjeza Gjino

Title: Chief Financial Officer

Cyclerion Reports Corporate Update and Full Year 2022 Financial Results

CAMBRIDGE, Mass., March 22, 2023 — Cyclerion Therapeutics, Inc. (Nasdaq: CYCN) today announced corporate updates including advances in its zagociguat (formerly CY6463) mitochondrial disease program.

The Company previously reported clinical data in adult patients with MELAS* that indicate that zagociguat may have potential as a first-ever therapy for patients with this rare, genetic mitochondrial disease. In Q4 2022, Cyclerion met with the United States Food and Drug Administration (FDA) and incorporated feedback from regulatory and mitochondrial disease clinical experts to refine the design of a Phase 2b study to evaluate zagociguat in patients with MELAS. More recently, Cyclerion filed a request with the FDA for Orphan Drug Designation and manufactured drug product to support the Phase 2b study.

Given the significant capital and capabilities necessary to ensure that the Phase 2b study is executed efficiently and with the highest quality, and the currently unfavorable capital market conditions, the Company is actively evaluating the best combination of capital, capabilities, and transactions available to it to advance the development of zagociguat and its other clinical development candidates and to maximize shareholder value.

Cyclerion is working expeditiously to deliver this potential treatment to help address the immense unmet needs of patients with MELAS, a patient population in desperate need of therapies. The Company is also working to develop and execute on the optimal strategy to advance its other wholly-owned assets: CY3018, a next-generation CNS-penetrant sGC stimulator that preferentially targets the brain and has demonstrated a unique pharmacological signature and promising profile for neuropsychiatric diseases, and olinciguat, a vascular-targeted sGC stimulator which has attractive profile in cardiovascular and cardiopulmonary diseases, areas where sGC stimulators have previously demonstrated clinical benefit.

Financial Position

- Cash, cash equivalents, and restricted cash balance on December 31, 2022 was approximately $13.4 million, as compared to approximately $20.4 million on September 30, 2022.
- Research and development expenses were approximately $31.5 million for the full year 2022, as compared to approximately $37.6 million for the full year 2021. The decrease of approximately $6.1 million was driven by decreases of approximately $1.0 million in non-cash stock-based compensation, approximately $0.3 million in salaries and other employee-related expenses, and approximately $6.8 million of facilities and operating costs, partially offset by increases of approximately $2.0 million related to zagociguat and CY3018 external research and development costs.

- General and administrative expenses were approximately $14.5 million for the full year 2022, as compared to approximately $20.6 million for the full year 2021. The decrease of approximately $6.1 million was driven by decreases of approximately $2.3 million in non-cash stock-based compensation, approximately $1.0 million in salaries and other employee-related expenses, approximately $2.1 million in facilities and operating costs, and approximately $0.7 million in outside professional and corporate expenses.
- Net Loss: Net loss was approximately $44.1 million for the full year 2022, as compared to $51.6 million for the full year 2021.

About Cyclerion Therapeutics
Cyclerion Therapeutics is a biopharmaceutical company on a mission to develop treatments for serious diseases. Cyclerion's portfolio includes novel sGC stimulators that modulate a key node in a fundamental signaling network in both the CNS and the periphery. The multidimensional pharmacology elicited by the stimulation of sGC has the potential to impact a broad range of diseases. Zagociguat is a CNS-penetrant sGC stimulator that has shown rapid improvements across a range of endpoints reflecting multiple domains of disease activity, including mitochondrial disease-associated biomarkers. CY3018 is a CNS-targeted sGC stimulator in preclinical development that preferentially localizes to the brain and has a pharmacology profile that suggests its potential for the treatment of neuropsychiatric diseases and disorders. Praliciguat is a systemic sGC stimulator that is licensed to Akebia and being advanced in rare kidney disease. Olinciguat is a vascular sGC stimulator that the Company intends to out-license for cardiovascular diseases. For more information about Cyclerion, please visit https://www.cyclerion.com/ and follow us on Twitter (@Cyclerion) and LinkedIn (www.linkedin.com/company/cyclerion).

Forward Looking Statement
Certain matters discussed in this press release are "forward-looking statements". We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should", "positive" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company's statements regarding the assessment of the best combination of capital, capabilities, and transactions available to it, the success of any such potential transactions in delivering any future value to the Company, the sufficiency of any expected revenues to provide liquidity and capital resources to pursue any of our go-forward business plans regarding any product candidate, the potential for zagociguat in the treatment of MELAS, the potential for CY3018 in the treatment of CNS diseases, the potential for olinciguat in the treatment of cardiovascular and cardiopulmonary diseases, the potential for any successful development of any of our assets, and other trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the success of any transactions in delivering any future value to the company, our ability to succeed with any go-forward business, the sufficiency of any expected proceeds to provide liquidity and capital resources to pursue any of our go-forward business plans regarding any product candidate (including without limitation our ability to fund additional clinical trials); any ability to successfully demonstrate the efficacy, safety and therapeutic effectiveness of any product candidate; any results of clinical studies not necessarily being indicative of or supported by the final results of subsequent clinical trials; the timing of and ability to pursue, obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, product candidates; the Company's ability to successfully defend its intellectual property or obtain necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company's research and development programs and collaborations; the success of the Company's license agreements; the acceptance by the market of the product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors

discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.
* MELAS (Mitochondrial Encephalopathy, Lactic Acidosis, and Stroke-like episodes syndrome)

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